Is the general consumer interest a source of legitimacy for healthcare regulation? An anaysis of the Dutch experience

Sauter, W.

Published in:
Revue Européenne de Droit de la Consommation = European Consumer Law Journal = Revista Europea de Derecho del Consumo

Publication date:
2009

Document Version
Publisher's PDF, also known as Version of record

Is the general consumer interest a source of legitimacy for healthcare regulation? An analysis of the Dutch experience

Wolf Sauter[1]

Introduction

Economic regulation by independent regulatory authorities is generally legitimised with reference to legal theories based on delegation, (partial) ministerial responsibility and judicial review, or more recently based on regulatory contracts and stakeholder representation. None of these models is fully satisfactory. They all focus either on the relationship between the regulator and the central authority, or on that of the regulator with the parties that are the subject of regulation looking at producer interests. In doing so they hardly take into account the ultimate objective of economic regulation itself : in particular the role of the consumer – and the consumer interest – generally receives little attention.

The Dutch Healthcare Market Regulation Act (Wmg)[2] creates a new starting point because it not only introduces the general consumer interest as a legal concept in the context of healthcare liberalisation but as the priority objective of regulation by the Dutch Healthcare Authority (NZa) – albeit based on a motivation that is largely implicit. This article proposes that an investigation into the interpretation of this concept is warranted, using *inter alia* an economic approach to regulation (based on the concept of market failure). This extends to asking whether the consumer interest can provide a source of legitimacy based on the results achieved in serving the statutory constituency of the regulator : the consumer.

It is proposed here that by applying a legal perspective to the role of the general consumer interest in the context of demand-driven markets and by making explicit the underlying economic assumptions, a contribution can be made to the theoreti-

[1] Professor of healthcare regulation, Tilburg Centre of Law and Economics (TILEC) and competition expert, Dutch Healthcare Authority (NZa). This text is a revised and edited version of my inaugural lecture at the University of Tilburg of 6 February 2009. All opinions expressed here are personal.

[2] (*Wet marktordening gezondheidszorg*) Law of 7 July 2006, *Official Journal* (*Staatsblad*) 415. Last amended 29 december 2008, *Official Journal*, 606.

cal foundation of healthcare regulation and of economic regulation more generally, as well as possibly its legitimacy. If this effort is successful it could be elaborated to improve the methods and the priority setting of (independent) regulators.

This approach is not just innovative because it focuses on the general consumer interest as a legal concept in order to legitimise regulatory supervision, but also as it draws on economic insights to do so. So far the NZa model of an independent regulatory authority for healthcare remains unique in the EU, as appears to be the case for the explicit focus on the general consumer interest. At the same time both healthcare reform and the consumer interest are already topical research themes. Hence this approach could be of interest beyond healthcare, and beyond the Dutch context.

The structure of this article is as follows : first, some background is provided on healthcare regulation in The Netherlands and the role of the general consumer interest in that context; next, market failure as an argument for economic regulation is discussed; followed by a short overview of behavioural law and economics issues in the healthcare context. Finally, the legitimacy of healthcare regulation is discussed; followed by conclusions.

I. Background

The main change introduced by the new healthcare system in The Netherlands in 2006 is the central role attributed to demand, and therefore to the consumer as the source of this demand [3]. The consumer is also perceived as requiring a certain measure of protection. At this point the general economic consensus in favour of demand-driven markets converges with a broader political trend which sees the consumer, and consumer protection, as important subjects of public policy in a market-based society.

The creation of the NZa (likewise in 2006) should also be seen in the context of the political ambition to replace centralised planning and control by regulated

[3] *Cfr Health insurance in the Netherlands : the new health insurance system from 2006*, ministry of Health, Welfare and Sport, September 2005 (http ://www.minvws.nl/en/folders/z/health-insurance-in-the-netherlands-2.asp), 78 p. For a general theoretical treatment of such an approach to healthcare : J. Le Grand, *The other invisible hand : delivering public services through choice and competition* (Princeton University Press, 2007). For a comparative view on competition in healthcare : "Improving health care : a dose of competition", report by the Federal Trade Commission (FTC) and the Department of Justice (DOJ), July 2004 (http :// www.usdoj.gov/atr/public/health_care/204694.htm).

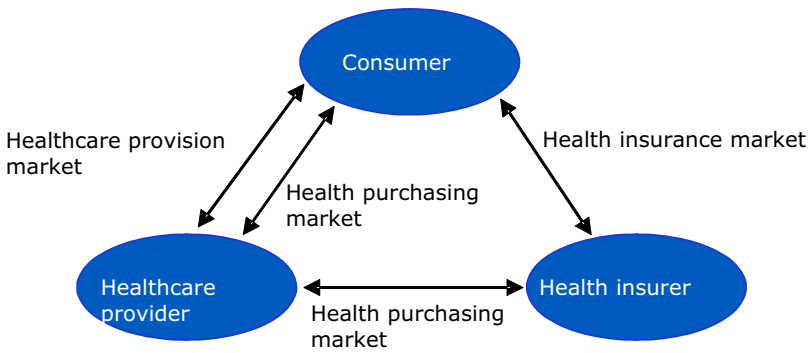
markets [4]. However the legislator considered the application of general competition policy instruments by the Dutch Competition Authority (NMa) insufficient, because the NMa lacked the tools to generate and promote competition in healthcare markets where competition did not yet exist. Hence the creation of the NZa as a sector-specific regulator forms an alternative both to the classic system of detailed regulation, and to relying on general competition policy.

A. Tasks of the NZa

The tasks of the NZa are set out in the Wmg and can be summarised in the following five categories.

1. Market supervision and market development with respect to the so-called "healthcare triangle" (figure 1). This covers sector-specific competition powers concerning parties with significant market power (SMP); the power to intervene in (and modify) agreements between different parties in health markets and in the manner in which these agreements come about (*e.g.* imposing auctions); the power to collect and disseminate information to promote transparency; and monitoring market developments to advise the Minister for Health and/or inform NZa policy.

FIGURE 1
The "healthcare triangle"



[4] "Founding of the health authority", letter from the minister for Health of 27 May 2005, Lower House of Parliament, parliamentary documentation 2003-2004, 29 324, no. 3; and *idem*., "De Nederlandse Zorgautoriteit : marktmeester in wording. Visie van de minister van Volksgezondheid op de Nederlandse Zorgautoriteit".

2. Tariff and performance regulation – setting prices and budgets and defining different types of products, enabling transactions between different parties in healthcare markets.

3. Supervision of the lawful execution by health insurers of the Health Insurance Act (Zvw), in particular the requirements of the duty of care (obligation to provide the services constituting the compulsory health insurance package), open enrolment (no risk selection) and community rating (no differentiation in premiums).

4. Supervision of the lawful and effective execution of the Act on Long Term Care (AWBZ).

5. Advising the Minister for Health, both on request and *ex officio*, concerning developments in health markets and related policy requirements (also : "advocacy").

In other words, as the authority responsible for the functioning of health markets within the new healthcare system the NZa combines regulatory (rule making), supervisory, executive, enforcement and advisory (or advocacy) functions.

B. Tensions between rule making, supervision and enforcement

Moreover the NZa is an independent regulatory authority which is not required to accept instructions in individual cases from the minister for Health. Its decisions in such individual cases are only subject to judicial scrutiny. Because the NZa combines the tasks listed above and enjoys the status of independent authority it is also called a market regulator (in the EU similar market regulators are typically found in liberalised sectors : *e.g.* the utilities, such as electronic communications and energy).

The Dutch government considered it necessary to combine these functions within the NZa in order to ensure that the NZa could develop a comprehensive view of the sector. This, in spite of the criticism by the Council of State, that combining rule-making with supervisory and enforcement powers was undesirable as it would compromise the independence of the NZa's supervision and enforcement functions.

There are also more practical objections against combining supervision and rule-making functions. Rule-making is based on horizontal discussions concerning different regulatory models or options with the regulated parties, whereas supervision is based on a vertical relationship of authority that can undermine support for the rule-making function. *Vice versa* there is a risk that the vertical relationship will be overshadowed by horizontal deliberation to a degree that endangers the

supervisory function. Moreover the vertical relationship must be based on the application and enforcement of rules that are clear to all concerned in advance – whereas the horizontal relationship is based instead on a process of "give and take" that is more discretionary in nature.

Hence, there is an uneasy balance between the more consensual practices that prevail in rule making and the authority function, if combined in a single regulator. In addition, this can lead to regulatory uncertainty, which is particularly undesirable in emerging markets (such as healthcare markets). This is because such uncertainty reduces the incentives to invest and/or to enter such markets, to the benefit of incumbents and the detriment of consumers. Consequently, it will be important to see whether the NZa manages to establish both its own independence and regulatory certainty in the sector.

This gives rise to questions such as the following ones : *a*) is combining these functions in fact necessary for the effectiveness – a key source of legitimacy for an independent regulator – of the NZa? *b*) How might the NZa enable the Minister for Health to discharge himself of his accountability to Parliament with regard to supervision and enforcement in individual cases – although he cannot give the NZa direct instructions? *c*) What standard will the administrative courts apply to judge the different activities of the regulator – in particular in relation to the legality test?

It is too early to answer these questions in detail now. Instead, it is proposed to investigate whether such institutional issues can usefully be seen through the prism of the general consumer interest, discussed below.

C. The general consumer interest

Key to the proposed perspective is that the NZa's legal charter requires it to be guided in the execution of all of the abovementioned tasks by the general consumer interest [5], which it translates in the three public interest dimensions of affordability, accessibility and quality [6].

[5] Article 3, fourth paragraph Wmg. This provision was introduced by Parliamentary amendment, as were the reference to information asummetry and market power discussed below. Lower House of Parliament, parliamentary documentation 2005-2006, 30 186, no. 42. Although many regulators appear to share these objectives *de facto* they are rarely set out in law and related directly to the general consumer interest.

[6] These three dimensions are derived from the explanatory text to the Health Market Regulation Act (Wmg), Lower House of Parliament, parliamentary documentation 2004-2005, 30 186, no. 3, page 2.

One of the issues to be addressed is whether there is tension between the interest and/or rights of the individual consumer and the general consumer interest. Another is whether such tension exists between the consumer interest in the short term and the long term. In both cases the question is how the regulator would go about deciding between them. The intuition is that the regulator would choose to defend the general consumer interest, and for the long term – however in terms of justifying decisions this also means dealing with increased uncertainty (*e.g.* in terms of a cost/benefit analysis).

As is usually the case in general competition policy as well, this indeed appears to be the case here too. (Different from the consumer perspective of general competition policy is that this tends to include – and concentrate on – intermediate producer interests, whereas for the NZa consumers are end-users *c.q.* final consumers.) Hence, what is intended as the objective of regulation by the NZa is not the classical consumer interest in terms of individual consumer rights and protection thereof, but a general economic interest at a more aggregated level, and in the sense of market participant within the healthcare triangle [7]. This means that promoting the general consumer interest is not primarily intended to promote the interests of consumers directly, but rather to ensure the market mechanism works effectively, which in turn leads to improved outcomes for consumers. The market perspective therefore is of central importance here.

Consistent with this approach, the NZa does not regard the individual consumer as an interested party with legal standing and the right to appeal (although consumer and patients' organisations operating on a nation-wide basis may enjoy this status [8]). However, even if the NZa is only required to promote the general consumer interest, this does not yet explain how it will make choices if the different dimensions of the general consumer interest are at odds (*e.g.* increased affordability may

[7] *Cfr* M. ARMSTRONG, "Interactions between competition and consumer policy", (2008) *Competition Policy International* 97, K.J. CSERES, "The Controversies of the Consumer Welfare Standard", (2007) *The Competition Law Review* 121; R. SMITH and S. KING, "Does competition law adequately protect consumers", (2007) *European Competition Law Review* 412; N.W. AVERITT and R.H. LANDE, "Consumer sovereignty : a unified theory of antitrust and consumer protection law", (1997) *Antitrust Law Journal* 714.

[8] Article 105 second paragraph Wmg. It is remarkable this only applies to decisions where (individual) "consumers and patients may be interested parties" whereas the original purpose was to exclude that they could be. How will this provision be interpreted in court? This provision was also introduced by Parliamentary amendment. Lower House of Parliament, parliamentary documentation 2005-2006, 30 186, no. 51.

decrease accessibility and/or quality, and *vice versa*) [9]. There may also be tensions between the role of consumers as insured persons and as patients receiving care, *i.e.* vis-à-vis health insurers and healthcare providers.

These observations give rise to the following questions :

Institutional questions : in the first place the institutional issue arises whether protecting the general consumer interest may play a legitimising role with respect to the different functions of the NZa as an independent regulator that were discussed above – and with respect to the accumulation of these functions, which may compensate for possible objections from a perspective of checks and balances ? Does the statutory objective of the general consumer interest function as a commitment which increases the credibility of NZa policies with respect to market parties ?

Substantive questions : the second theme is how this general consumer interest may be operationalised in terms of the three public interest dimensions and balanced against the interests of health insurers and providers of care, in more substantive terms. This will involve looking at *e.g.* : interest representation, rule-making, including interpreting "open norms", supervision and enforcement.

An important point of reference is the following instruction from the preamble to the Wmg :

"that it is desirable, considering the information lag of consumers and the imbalance of power between the parties in healthcare, to protect and promote the position of the consumer".

This text, clearly linked with the obligation of the NZa to promote the general consumer interest, marks three important dimensions. The first concerning the relationship between the concepts of the consumer interest and market failure in the economic context of demand-driven system. The second, concerning the need to compensate for information lag and market power taking into account the bounded rationality of the (individual) consumer. The third concerning the legitimacy of the NZa.

Market failure is dealt with first as it can feed into the legal discussion on legitimacy, and provides a background to the concept of bounded consumer rationality that is treated next.

[9] It may well be possible to make the necessary comparisons based on QALYs ("quality adjusted life years"). *Cfr* D. Dranove, *What's your life worth ? Health care rationing… Who lives ? Who dies ? And Who decides* ?, FT Prentice Hall, 2003 ; D.M. Cutler, *Your money or your life. Strong medicine for America's healthcare system*, Oxford University Press, 2004.

II. Market failure as an argument for economic regulation

Firstly, the two elements mentioned above, information lag (or information asymmetry) and imbalance in market power, are two important types of market failure. In economic terms, existence of market failure is generally required before public intervention can be justified. At the same time healthcare liberalisation aims to increase the efficiency and effectiveness of healthcare provision. That cannot be achieved where healthcare markets fail.

A. Market failure

Market failures in healthcare involve *e.g.* : *a*) Market power of certain parties, such as hospitals enjoying a regional monopoly; *b*) information asymmetry, such as doctors who know more about the usefulness of a specific treatment than consumers or insurers; *c*) adverse selection, such as healthy consumers who do not want to take out insurance while insurers prefer to refuse consumers who are ill; *d*) moral hazard, where third parties are made to bear the cost of behaviour, such as pharmacists receiving bonuses from the drug industry for providing consumers with more expensive branded medication rather than less expensive generics with the same active ingredient.

This illustrates there are multiple sources of market failure in healthcare, so regulation to address them may be justified. The fact that the Wmg explicitly links two important forms of market failure to public intervention in the consumer interest underlines the relevance of this perspective.

B. Regulation

Although economic theory does not provide an unequivocal answer to the question how regulation should be applied [10], it does provide a framework that facilitates making choices when designing regulation. This concerns, *e.g.* :

– static objectives *versus* dynamic objectives (which can also be summarised as short term versus long term objectives), generally with important implications

[10] R. Baldwin and M. Cave, *Understanding regulation : theory, strategy and practice,* Oxford University Press, 1999; A.I. Ogus, *Regulation : Legal Form and Economic Theory*, Clarendon Press, 1994; A. Shleifer, "Understanding regulation", (2005) *European Financial Management* 439.

for incentives for innovation and investments more generally – for example when balancing quality and affordability in healthcare markets;

- the consumer surplus *versus* the producer surplus/total welfare, again with regard to innovation (involving such questions as allowing the distribution of dividends *versus* retaining invested funds in the healthcare sector);
- efficiency *versus* equity, such as income effects and redistributive questions : are healthcare providers allowed to retain efficiency gains or are such rents skimmed off? (and the effects of budgetary measures on efficiency);
- total welfare *versus* components thereof such as the three distinct dimensions of the public interest in healthcare : affordability, accessibility and quality. Here the main question is how to weigh these factors in the event that the effects on them (positive or negative) differ?;
- primary objectives (welfare) against secondary objectives, such as protecting smaller providers or new entrants, income policy, regional and local interests (such as the spatial distribution of facilities – and therefore accessibility).

This short list suffices to illustrate that choices are involved which are also relevant to decisions involving the general consumer interest in healthcare with respect to the three variables affordability, accessibility and quality. By examining what the underlying economic choices are, decisions made in relation to the public interest variables can be better understood, and can be motivated more coherently.

Hence it is suggested that economic theory on regulation and market failure should be used to interpret the objectives of the Wmg and the way in which the NZa applies them (in particular concerning information asymmetry and market power).

III. Dealing with bounded consumer rationality

A. Behavioural law and economics

Behavioural economics teaches us that consumer behaviour is subject to bounded rationality [11]. This is certainly true in healthcare. Consumers hardly investigate the

[11] D. Kahneman, "Maps of Bounded Rationality : Psychology for Behavioral Economics" (2003), *American Economic Review* 1449; D. Kahneman, and A. Tversky (éd), *Choices, Values and Frames*, Cambridge University Press, 2000. Many of the insights in this field are derived form the analysis of financial services (behavioural finance). *Cfr* A. Shleifer, *Inefficient Markets : An*

care offered to them, although there are large differences between providers in terms of quality (including key outcomes such as survival rates, *i.e.* mortality). Hence they are likely to spend far more time researching the purchase of a new car than to find out where they should undergo their heart surgery [12]. Admittedly, the latter is much more difficult given the lack of transparent information, and because, in The Netherlands, the norm is that all healthcare consumers receive equal treatment – which ought to mean there are no differences on quality. Reality however, is different [13]. And in view of this fact the demand of consumers for the information that is necessary to make an informed choice should be greater. The same is true for less intrusive forms of care and for selecting a health insurance policy. In the absence of such informed choice the prospects for demand-driven market-based reform or indeed for public health (and with negative external effects for society at large) are dire.

Classical economic explanations for these problems such as search costs and information asymmetry remain relevant but are being supplemented with psychological factors by behavioural economics. This school of thought is based on the principle that the classical rational consumer or *homo economicus* does not exist, not even at an aggregated level. Consumers tend to overestimate the risk of minor adverse events and to underestimate more serious dangers (a behavioural characteristic that gave rise to the expression "penny wise and pound foolish"). Once consumers own a particular item they are likely to value it much more highly than before they did. They are subject to irrational forms of peer pressure. Meanwhile, the framing of choices and the default setting have a strong impact on consumer behaviour (something the Dutch Ministry of Health has tried to exploit in order to

Introduction to Behavioral Finance, Clarendon Lectures, Oxford University Press, 2000. A link with law and economics is found in R.H. THALER and C.R. SUNSTEIN, *Nudge : Improving decisions about health wealth and happiness*, Yale University Press, 2008 ; C.R. SUNSTEIN (ed), *Behavioral law and economics*, Cambridge series on judgment and decision making, Cambridge University Press, 2000.

[12] *Cfr* M. GAYNOR, "What do we know about competition and quality in healthcare markets ?", NBER Working Paper no. 12301, June 2006, http ://www.nber.org/papers/w12301.pdf ; M. GAYNOR, *Competition and quality in healthcare markets – Foundations and trends in microeconomics series*, Now Publishers, 2007. M. PORTER and E. OLMSTED-TEISBERG, *Redefining healthcare : creating value-based competition on results*, Harvard Business School Press, 2006.

[13] In The Netherlands mortality rates for the bundle of treatments that accounts for 80 % of hospital deaths differ by 200 % between the best and worst performing participating hospitals (after case-mix adjustment). Including the non-participating hospitals is believed to increase this difference to 400 %. If figures are disaggregated by treatment the differences in mortality rates are likely to be higher still. *Cfr* http ://www.prismant.nl/Kwaliteit_en_Veiligheid/Dossiers/HSMR.

promote organ donation and to obtain permission to use private data in the electronic patient file). As any marketing professional is aware, exploiting these psychological weaknesses can be turned into a money spinner. In the context of healthcare the effects of bounded consumer rationality are not just costly, but painful – or even deadly.

B. The role of intermediaries

One way of solving such problems is for certain parties to adopt the function of searching for the optimal solutions for others, based on specialisation and/or the aggregation of interests. By purchasing on a larger scale their experience and market power increases, and hence their bargaining position of such intermediaries vis-à-vis providers of care is strengthened (allowing them to obtain yet better results).

In a healthcare context this usually involves not just patients' and consumer organisations but especially healthcare insurers who can compensate both for the market power and the information advantages enjoyed by providers of care. In order to play this role effectively health insurers have to be able to direct their customers effectively : in order to be credible they have to reward healthcare providers that perform well by offering them more turnover and therefore more customers (while punishing those who perform badly with fewer or no customers). Moreover they must offer healthcare providers the possibility to specialise and improve their quality by offering them more consumers with specific ailments. This too means these consumers will not go elsewhere. The implied logic is that as long as consumers can choose between different competing healthcare insurers, these insurers will put pressure on healthcare providers, which in turn, for instance in the case of hospitals, will put pressure on consultants (medical specialists).

In this manner a "chain" of competitive pressure forms, which requires consumers to make an independent choice only at the first (and relatively straightforward) level between different healthcare insurers. This has a positive effect on the information lag of consumers, promotes the balance of power in the marketplace for healthcare services and compensates for (or prevents) "irrational" consumer behaviour.

C. Tensions between the individual and general consumer interest

This does beg the question whether selective contracting of preferential providers of care and/or requiring co-payments or even excluding care outside the network of preferred providers is regarded [14]. There is tension here between, on the one hand, the right of the individual consumer to freely choose his or her provider of care and on the other hand effective demand-driven care at a systemic level, respectively : a tension between the individual and the general consumer interest [15]. A comparative problem arises in relation to preferential purchasing policies of healthcare insurers with respect to generic drugs (to contain costs) and the personal preferences of individual consumers for more expensive branded drugs with the same active component. In both cases tension also arises between the three public dimensions of the general consumer interest – because directing consumers may improve affordability and/or quality, but it restricts accessibility.

The logic of collective action is also at odds with another general assumption in economics : that the sum of knowledge that is represented by the decisions of individual consumers is larger than that of a central actor (such as the state or of another collective). From this perspective it is questionable whether the NZa will be able to predict and compensate for the effects of the bounded rationality of consumers in its role as regulator. The intuition on this point is that the solution would be to promote the freedom of choice of consumers between different competing insurers and healthcare providers : making markets work. This is consistent with the role of the NZa as regulator, *i.e.* at systemic level.

IV. The legitimacy of healthcare regulation

Second, the question arises whether it is possible to link the general consumer interest with the legitimacy of the NZa. In other words : would it be possible to derive the legitimacy of the NZa from the effectiveness of its actions in terms of accessibility, affordability and quality, and in the interest of its statutory constituency – the consumer?

[14] For an account of the US experience in this respect *cfr* D. Dranove, *The Economic Evolution of American Healthcare : from Marcus Welby to Managed Care*, Princeton University Press, 2002; and *A Dose of Competition*, above note 2.

[15] In this context economists generally employ the familiar concept of a "veil of ignorance" to justify choosing the perspective of the general consumer interest. J. Rawls, *A Theory of Justice,* Harvard University Press, 1971.

A. Different theories on the sources of legitimacy for regulation

In addition to the economic justification for regulation based on the concept of market failure mentioned above, there are several different legal approaches with respect to the legitimacy of market supervision by independent regulators [16]. In the first place this can be linked to the (democratically legitimised) legal mandate of the regulator and/or the indirect parliamentary scrutiny exercised via the (Dutch legal doctrine of) ministerial responsibility. The idea is that the Minister is accountable both for his own policy and for general rules made by the regulator. In this context especially the "open norms" that are often used given the complexity or unpredictability of the subject matter and which the regulator must interpret, create difficulties. In addition it is not yet clear to what extent the Minister will be held accountable for supervision and enforcement by the independent regulator in individual cases. In view of the accountability gap that may arise as a result, judicial review of individual regulatory decisions remains especially important.

A novel perspective on legitimacy of regulation focuses on the notion of a *regulatory contract*, that is concluded between the parties that are subject to regulation on the one hand, and the regulator on the other. Other recent theories are based on horizontal regulation, in which case the various stakeholders jointly determine the meaning and content of open norms : according to this approach, in the final instance the regulator is even accountable for his actions to the stakeholders. This in effect leads to a form of "direct democracy" at sector level. Such horizontal theories of regulation have been gaining ground recently. From the European context, where the (perceived) lack of democratic legitimacy is a well-known problem, theories of governance are emerging that focus on regulatory procedures as a possible source of legitimacy, also in relation to self-steering networks of regulators [17].

B. Market power and interest representation

However, the relations between regulators and interest groups are far from neutral. Both political theory and economics teach us that relatively small but concen-

[16] *Cfr* T. Prosser, "Regulation and social solidarity", (2006) *Journal of Law and Society* 364; T. Prosser, "Theorising utility regulation", (1999) *Modern Law Review* 196; Baldwin and Cave, above note 9.

[17] *Cfr* European Commission, White Paper on European Governance, COM(2001) 428, *O.J.,* 2001, C 287/1; G. Majone, "The regulatory state and its legitimacy problems", (1999) *West European Politics* 1; M. de Visser, *Network-based Governance in EC Law*, Hart Publishing, 2009.

trated interests – usually producer interests – are often capable of dominating the political arena at the expense of much larger but diffuse general interests – such as the consumer interest [18]. As a result so-called "iron triangles" may form between interest groups, segments of parliament, and the responsible bureaucracy [19].

At the same time, regulators are usually created precisely in those instances where there are fundamental problems of market power and/or of market structure. Hence in these cases there are stronger and weaker market participants, and the former tend to leverage their position of market power – in many cases strengthened and fostered by the pre-existing legal framework – at the expense of entrants, and above all at the expense of consumers. It is this situation that a regulator is called upon to remedy : even apart from a formal legal mandate to this effect (such as exists for the NZa). For instance introducing more efficiency also means breaking up collusive practices, mitigating market power and promoting market entry.

The regulator is charged with compensating for inequalities resulting from market power or advantages derived from the market structure. It seems evident that that for regulators therefore the consumer interest should come first – in the case of the NZa as an explicit requirement. This is logical in an economic sense (from a perspective of effective competition), but also in view of the political theory mentioned earlier – and even from the "access to justice" approach in the sociology of law [20].

C. Focusing on objectives and results

In other words, there is tension between on the one hand the regulatory responsibilities that require wide powers (including rule making powers and open norms) and on the other had the limited possibilities for democratic legitimation of – and democratic control over – these powers based on Ministerial responsibility vis-à-vis Parliament. Attempts to compensate for this by means of transparency, participation and consultation as a form of direct democracy appear to be at odds with

[18] M. Olson, *The Rise and Decline of Nations : Economic Growth, Stagflation, and Social Rigidities,* Yale University Press, Newhaven 1982. *Cfr* J.E. Stiglitz, "The Theory of Economic Regulation", (1971) *Bell Journal of Economics* 3; R.A. Posner, "Theories Of Economic Regulation", (1974) *Bell Journal of Economics* 335.

[19] G. McConnell, *Private Power and American Democracy*, Alfred A. Knopf, New York 1966.

[20] Seminal : M. Galanter, "Why the 'haves' come out ahead : speculations on the limits of legal change", (1974) *Law and Society Review*. Reprinted in R. Cotterrell (ed), *Law and society,* The international library of essays in law and legal theory 13*,* Ashgate, Aldershot 1994, 165.

the requirement that the regulator should confront vested interests and inequality between market participants (as the result of market power or market structure), for the benefit of the general consumer interest.

Hence the NZa will not have the choice of filling in the open norms that are part of its legal framework in the course of deliberation with the parties that are subject to its regulatory powers. Moreover regulators are in principle created in those instances where there is political agreement on the basic principles, so these can legitimately be withdrawn form the realm of direct democratic control : such norms are not subsequently freely negotiable with market parties. Also, (independent) regulators are held accountable in terms of (quantifiable) results – which in turn are a source of legitimacy and can be expressed in terms of achieving objectives (*e.g.* the three dimensions of the general consumer interest). This requires making these three dimensions comparable and reasoning decisions in these terms, in relation to the various outputs produced by the regulator : rules, decisions, opinions and advice (and the court decisions reviewing them).

Conclusions

As has been described above the various current legal theories concerning the legitimacy of regulation are not satisfactory, in particular for independent regulators. It is proposed that they should be supplemented by economic theories of regulation based on the concept of market failure. In this context the concept of the general consumer interest is of particular interest.

This can be seen in the context of healthcare regulation in The Netherlands. For the NZa, the general consumer interest is not just one among several interests of the same order of significance as that of other market participants. Instead it is a statutory priority and therefore determines the approach of the regulator both in the context of rule-making and in specific cases. This means that the NZa is unable to make its regulation negotiable with market players. Instead it is charged with redressing the balance of power to the advantage of the consumer and to compensate for the latter's information lag.

The NZa has chosen to fill in the abstract notion of the general consumer interest by means of the three public interest dimensions of affordability, accessibility and quality. The next step should be quantifying these variables. This is necessary to allow them to be compared in an objective manner, in particular in those cases when the effects on one variable are positive, and on another negative. It is expect-

ed that as a consequence not only (judicial) review of NZa decisions will be facilitated but that the NZa will also gain additional legitimacy in terms of obtaining verifiable results.

Liberalisation and competitive provision of healthcare are at the forefront of the debate on the relationship between the private and the public spheres, and The Netherlands has so far gone furthest in healthcare liberalisation in the EU. Developing the concept of the general consumer interest – fleshing out the dimensions of quality, accessibility and affordability – will contribute to understanding the new role of regulation in providing "social services". Therefore it is expected these preliminary findings, and directions of future research, may be of interest in other sectors and other jurisdictions as well.